Case No.: Klein-084B

TITLE OF THE INVENTION

INFILTRATION PUMP HAVING INSULATED ROLLERS AND PROGRAMMABLE FOOT PEDAL

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] The Present application is a continuation-in-part application of pending United States Application Serial Number 10/422,299 filed April 24, 2003 entitled INFILTRATION PUMP HAVING INSULLATED ROLLERS AND PROGRAMMABLE FOOT PEDAL, the disclosure of which is expressly incorporated herein by reference.

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

NOT APPLICABLE

BACKGROUND OF THE INVENTION

[002] The present invention relates in general to an improved tumescent anesthesia apparatus and, more particularly, to a tumescent anesthesia infiltration pump including insulated rollers and a foot pedal with a programmable response.

[003] Liposuction is an invasive surgical procedure for removing subcutaneous fat cells by inserting one end of a liposuction cannula into an area of interest of a patient, and attaching the other end of the cannula to a suction device.

[004] It is common that when the fat cells are removed from the patient, blood is inevitably withdrawn. When the amount of the removed fat cells is low, withdrawal of blood is not critical. However, if the removal of a large volume of fat cells is required, complications result and recuperation time is extended and in almost all situations, supplemental blood is added to the patient, thus posing other danger.

[005] To increase safety of the procedure, the Applicant of the present invention, Dr. Jeffrey Klein first introduced the use of the tumescent technique for local anesthesia (Klein, JA, The tumescent technique for liposuction surgery, J Am Acad Comestic Surg 4:263-267, 1987). The tumescent technique involves the infiltration of a solution of extremely dilute lidocaine, epinephrine, and sodium bicarbonate into the subcutaneous fat. Infusion is made through the use of a peristaltic infiltration pump, and the tumescent solution reduces bleeding and also eliminates the need for general anesthetics.

[006] Currently, the peristaltic pump used in the tumescent anesthesia apparatus includes an electric motor and a headstock driven by the electric motor. The headstock allows the tube connecting the cannula extending there through and controls the flow direction of the fluid in the tube. The headstock is made of metal material, such that it is electrically conducted to the live circuitry of the electric motor. Therefore, during the liposuction operation, if the tube extending through the headstock has a breech, or when a

leakage occurs to the live circuitry of the electric motor, electric current may be delivered to the patient under operation; and thus causes great danger of the patient.

BRIEF SUMMARY OF THE INVENTION

[007] The present invention provides an improved liposuction apparatus, comprising a cannula, a peristaltic pump, a container containing a dilute solution of local anesthetic, a flexible sterile tube connecting the cannula to the container, and a footpad on-off switch. One end of the cannula is in fluid communication with the peristaltic pump via the flexible tube. The peristaltic pump includes a pathway allowing the flexible tubing to extend through and a plurality of non-conductive rollers installed along the pathway to exert force on the flexible tubing. The container is in fluid communication with the cannula via the flexible tubing extending through the peristaltic pump. A flexible non-sterile tube is further included to connect the foot pedal that contains an air bellow therein to the peristaltic pump to control operation by means of a pulse of air pressure. The infiltration apparatus further comprises a sensor in mechanical communication with the peristaltic pump, and a sound generating device in electrical communication with the sensor. The sensor is operative to detect either a liquid discharging rate from the pathway,

or the rotation speed of the non-conductive rollers. Upon detection of the flow rate or the rotation speed, the sensor generates and outputs an electrical signal to the sound generating device. The sound generating device then generates a sound with a frequency in response to the flow rate or the rotation speed. In one embodiment, the sound generated by the sound generating device includes a sequence of beeping sounds.

[008] In the above infiltration apparatus, the foot pedal is operative to switch on the peristaltic pump while being depressed and switch off the peristaltic pump while being released. Therefore, the operator/surgeon can actuate the infiltration of local anesthesia simply by continuously depressing the foot pedal. By simply releasing the foot pedal, the infiltration is stopped. This mode of controlling the infiltration pump is referred to as "momentary" mode. Alternatively, when the infiltration is continued for a longer period of time, the response of the foot pedal can be programmed into another mode referred as the continuous or toggle mode. Under this alternate (continuous) mode, the peristaltic pump is switched on and off in a toggle fashion by alternate depression performed on the foot pedal. That is, in response to each depression performed on the foot pedal, regardless the time the depression lasts, the peristaltic pump is either switched from on to off, or from off to on and remains the off/on status before a next depression event is performed thereon. Once the

foot pedal is depressed again, the peristaltic pump is switched to the opposite status and remains on/off before another depression event is performed. Additionally, the foot pedal may be operated under a rate control mode in which the flow rate of the fluid or the rotation speed of the pump is proportional to the duration of depression applied to the foot pedal.

[009] The peristaltic pump further comprises a rotation mechanism driving the non-conductive rollers to rotate clockwise or counterclockwise. As the rollers is made of an electrically non-conductive material, when there is inadvertent fluid leakage from the live circuitry of the peristaltic pump such as when there is breech on the wall of the flexible tubing, electric current is prevented from being delivered to the patient. Therefore, safer pump operation is provided.

[0010] In one embodiment of the present invention, the infiltration apparatus comprises a cannula, a flexible tubing connected to the cannula, an infiltration pump comprising a pathway for the flexible tubing to extend through and a plurality of rollers installed along the pathway to exert force on the flexible tubing, a container connected to the flexible tubing extending through the peristaltic pump, and a foot pedal operative to control the on/off status of the infiltration pump in response to depression performed thereon in a plurality of modes. For example, the infiltration pump is switched on when the foot pedal is depressed, and switched off when

the foot pedal is released under one of the modes (the momentary mode). In another operational mode (the continuous mode), the infiltration pump is switched and remains on continuously and off continuously by alternate depression performed thereon. Additionally, a rate control mode can also be selected to adjust the flow rate of the fluid flowing through the pump or the rotation speed of the pump by controlling the duration that the foot pedal is depressed. The infiltration apparatus further comprises a sensor in mechanical communication with the infiltration pump and a sound generating device in electrical communication with the sensor. The sensor is operative to detect the force exerted by the rollers and to generate an electric signal in response to the force. Upon reception of the electric signal, the sound generating device is then operative to generate a sound with a frequency determined by the force.

[0011] The present invention further provides an infiltration pump comprising a headstock, which comprises a pathway and a plurality of electrically insulated rollers installed along the pathway. The headstock further comprises a rotation mechanism operative to drive the insulated rollers rotating clockwise or counterclockwise, and the infiltration pump further comprises an electric motor operative to drive the rotation mechanism to rotate. The infiltration pump further comprises a sensor in mechanical communication with the pathway or the rollers, and a sound generating device in mechanical or electric

communication with the sensor. When the sensor is in communication with the rollers, the sensor is operative to detect a rotation speed of the rollers, so as to generate and output an electrical signal to the sound generating device. When the sensor is in communication with the pathway, the sensor includes a flow sensor operative to detect a flow rate of a fluid flowing through the pathway. Upon reception of the electric signal, the sound generating device generates a sound with a frequency in response to the rotation speed or the flow rate.

[0012] In one exemplary embodiment, an infiltration pump for fluid infiltration is provided.. The infiltration pump comprises a head stock and a rotation mechanism. The headstock includes a pathway and a plurality of rollers installed along the pathway. The rollers are fabricated from electrically non-conductive materials. The rotation mechanism is operative to actuate rotation of the rollers along a predetermined direction. To facilitate infiltration of a fluid, a flexible tubing is applied to extend through the pathway and in contact with the rollers. A switch or a foot pedal may be used to control rotation of the rollers, and a sensor can be used to detect the rotation speed of the roller. Preferably, a sound generating device is communication with the sensor to generate a sound with a frequency in response to the rotation speed of the rollers.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] These, as well as other features of the present invention, will become apparent upon reference to the drawings wherein:

[0014] Figure 1 shows an infiltration apparatus in use in an operating room;

[0015] Figure 2 shows a cross-sectional view of a headstock of the peristaltic pump of the infiltration apparatus;

[0016] Figure 3 shows a perspective view of the partially open peristaltic pump;

[0017] Figure 4 shows the infiltration pump insulated rollers of the peristaltic pump;

[0018] Figure 5 shows the structure of the foot pedal; and

[0019] Figure 6 shows the sensor and the sound generating device of the infiltration pump in one embodiment of the present invention; and

[0020] Figure 7 shows another block diagram of the sensor and the sound generating device of the infiltration pump in another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0021] The present invention provides an improved tumescent infiltration apparatus. As shown in Figure 1, the infiltration

apparatus comprises a peristaltic pump 11, a container 12, a flexible tubing 13, a cannula 14 and a foot pedal 16. The cannula 14 is attached to the peristaltic pump 11 via the flexible tubing 13. The flexible tubing 13 further extends through the peristaltic pump 11 and is connected to the container 12, such that fluid communication between the patient 15 and the container 12 is established. For the convenience of controlling the operation of the peristaltic pump 11, the tumescent infiltration apparatus further comprises a foot pedal 16 electromagnetically or pneumatically connected to the peristaltic pump 11. The function and operation of the foot pedal 16 will be further described in details later in this specification. It will be appreciated that, in addition to the foot pedal 16, the apparatus may comprise other control mechanism for allowing the user or the surgeon 10 to control and adjust the operation of the peristaltic pump 11.

[0022] As shown in Figure 1 and Figure 2, the peristaltic pump 11 has a headstock 17 controlling the flow direction and speed of the fluid inside the flexible tubing 13. The peristaltic pump 11 may further comprise a switching device accessible to the operator/ surgeon to select the required flow direction and speed of the fluid in the flexible tubing 13. The headstock 17 includes a pathway 19 through which the flexible tubing 13 extends, a plurality of rollers 25 installed along the pathway 19 to exert a force or pressure upon the

flexible tubing 13, a rotation mechanism 20 driven by a motor (not shown) of the peristaltic pump 11 to rotate. In this embodiment, when the rotation mechanism 20 rotates counterclockwise as shown in Figure 2, the rollers 25 are driven thereby to rotate counterclockwise. Thereby, a pumping force is exerted upon the flexible tubing 13 and the fluid therein flows through the flexible tubing 13 along the direction indicated by the arrows 24. Similarly, when the rotation mechanism 20 rotates clockwise, the rollers 25 are driven to rotate clockwise, such that the flow direction of the fluid in the flexible tubing 13 is reversed. Therefore, by controlling the rotation of the rollers 25, the operator or the surgeon can draw the tumescent solution in the container 12 to the patient, and aspirate the tissues/cells from the patient 15 to achieve cosmetic or even medical effect with greatly reduced risk since the tumescent solution and the removed tissue/cell have never been exposed in the atmosphere to cause contamination thereof. In addition to the flow direction, the flow rate of the fluid is also controlled by the rotation speed of the rollers 25.

[0023] Preferably, the flexible tubing 13 is made of flexible material such as polyvinyl chloride (PVC). The exposed part of the flexible tubing 13 is preferably transparent, such that the surgeon can monitor the flow of tumescent solution infiltrated into the patient 15. The part of the flexible tubing 13 extending through the peristaltic

pump 11 is preferably made of material which can withstand the force exerted by the rollers 25. The material includes Norprene, silicone, Tygon, Pharmed, or C-Flex, for example.

[0024] To perform the tumescent liposuction operation, infiltration of local anesthesia agent is required prior to aspirate fat and tissue from the patient. The tumescent solution is contained in the container 12, and the cannula 14 is inserted into an area of interest of the patient 15 through a small incision. In response to the foot pedal 16, the cannula 14 draws the tumescent solution from the container 12 via the peristaltic pump 11, and the infiltrated amount of the tumescent solution can be controlled through adjustment of the headstock, including the rotation direction and speed.

[0025] Figure 3 shows the partial interior structure of the headstock 17 of the peristaltic pump 11, and Figure 4 shows a perspective view of the rotation mechanism 20 and the rollers 25. In this embodiment, both ends the rollers 25 are interlocked with the rotation mechanism 20 by the plates 21. It will be appreciated that in addition to the specific arrangement as shown in Figure 3, other structure and connection between the rotation mechanism 20 and the rollers 25 can also be applied without exceeding the spirit and coverage of the present invention. Typically, the material of the rotation mechanism 20 and the plates 21 are made of metal, such that the rollers 25 are conductively linked to live circuitry of the peristaltic

pump 11 through the rotation mechanism 20 and the interlocking means. When the flexible tubing 13 has a breech which has not been noticed by the user or the surgeon, the electric current can thus be inadvertently delivered to the patient 15. Therefore, in the present invention, the rollers 25 are made of an electrically non-conducting material, so that even if there is a leakage current generated and flowing from the live circuitry of the peristaltic pump 11 to the rollers 25, electric current is prevented from being delivered to the patient 15.

[0026] Figure 5 shows the structure of the foot pedal 16 comprising a bellow that generates a pulse of air pressure while being depressed. As shown in Figures 1 and 5, the foot pedal 16 is connected to the peristaltic pump 11 via a hollow flexible tube 50. Therefore, when the foot pedal 16 is depressed or released, a response signal consisting of a pulse of air pressure is delivered to the peristaltic pump 11 via the hollow flexible tube attached to the foot pedal 50. The response signal of the foot pedal 16 can be programmed and selected according to specific need; and according to the response signal, the peristaltic pump 11 operates under different mode. A mode selector can be used to connect to the foot pedal 16 and select the pre-programmed response thereof. In this embodiment, the foot pedal 16 is programmed with three exemplary modes, including a continuous or toggle mode, an alternate momentary mode, and a rate control mode.

[0027] In the continuous or toggle mode, whenever the foot pedal 16 is depressed once and released, a response signal is output to continuously activate the peristaltic pump 11. That is, the infiltration procedure is continuously performed after the foot pedal 16 is depressed once and released afterwards. The infiltration procedure will not be terminated unless an inactivation signal is input to the peristaltic pump 11. More specifically, when the foot pedal 16 is depressed once, the infiltration procedure is initiated and continuously performed even the foot pedal 16 is released afterwards. When the foot pedal 16 is depressed again after being released, the infiltration procedure is interrupted or terminated. That is, regardless the duration of the depression upon the foot pedal 16, a response signal is generated to reverse the current operation status of the peristaltic pump 11. When the peristaltic pump 11 is currently on, the response signal switches off the peristaltic pump 11. In contrast, if the peristaltic pump 11 is currently inactive, the response signal activates the peristaltic pump 11. The reversed operation status is remained even when the foot pedal 16 is released. Before the foot pedal 16 is depressed again, the peristaltic pump 11 remains on or off as it was. Therefore, in the continuous mode the peristaltic pump 11 operates continuously until it is switched on/off by alternate depression performed on the foot pedal.

[0028] In contrast, under the momentary mode, whenever the foot pedal 16 is released, the response signal for activating the peristaltic pump 11 is no longer available. Or the response signal for inactivating the peristaltic pump 11 is output from the foot pedal 16 whenever the foot pedal pressure is released. Therefore, as long as the foot pedal 16 is depressed, the fluid is drawn from the container 12 to the patient, and the infiltration procedure is performed. On the contrary, whenever the foot pedal 16 is released, the peristaltic pump 11 stops operating, no fluid will be drawn from the container 12; and the infiltration procedure is interrupted or terminated.

[0029] The rate control mode can be combined to either the continuous mode or the momentary mode. In the rate control mode, the flow rate of the fluid drawn from the container 12 or the rotation speed of the peristaltic pump 11 is proportional to the duration that foot pedal 16 is depressed. That is, the longer the foot pedal 16 is depressed, the higher the flow rate of the fluid can reach. When the foot pedal 16 is depressed for a period of time until the fluid attains a preferred flow rate, once the foot pedal 16 is released, the fluid is infiltrated constantly at the preferred flow rate. The infiltration of the fluid will not be interrupted or terminated until further depression is applied to the foot pedal 16. Alternatively, the rate control mode can also be used in combination with the momentary mode. That is, when the foot pedal 16 is depressed for a period of time until the fluid

attains the preferred flow rate, once the foot pedal 16 is released, the peristaltic pump 11 stops rotating, or infiltration of the fluid stops. The infiltration of fluid or rotation of the peristaltic pump 11 will not resume until a further depression applied to the foot pedal 16.

[0030] The programmable response of the foot pedal 16 allows the operator/surgeon to select the suitable mode and flow rate of the fluid for operation. For example, when it is required to frequently switch on/off the peristaltic pump 11, the foot pedal 16 is programmed under the momentary mode that whenever the foot pedal 16 is depressed, the peristaltic pump 11 is switched on and actuated. To keep the peristaltic pump 11 in the on status, the foot pedal 16 must remain depressed. Once the foot pedal 16 is released, the peristaltic pump 11 is switched off, and the infiltration operation is stopped. When it is required to keep the peristaltic pump 11 activated for a longer period of time, the foot pedal 16 can be programmed into the continuous mode under which the peristaltic pump 11 is switched on and off for alternate depression by the operator/surgeon. That is, when the current status of the peristaltic pump 11 is off, by depressing the foot pedal 16, the peristaltic pump 11 is actuated and remains on even when the foot pedal 16 is released. By releasing and depressing the foot pedal 16 again, the peristaltic pump 11 is switched off. In addition to the continuous on/off mode and the momentary on/off mode, the rate control mode can also be selected to control the

flow rate of the tumescent solution according to the physical condition of individual patient; and thereby provides a safer and more efficient infiltration procedure.

[0031] During the operation, it is important to monitor the infiltration speed of the fluid. To prevent the operator surgeon from being distracted for reading the infiltration speed from a meter or instrument during the operation, the present invention further provides a sensor automatically detecting the infiltration speed, and a sound generating device generating a sound indicating the filtration speed. As shown in Figure 6, the sensor 60 is in mechanical communication with the peristaltic pump 17. The sensor 60 may be attached to the shaft of the rotation mechanism 20 or the axis of any of the rollers 25 as shown in Figure 2 to detect the rotation speed of the rollers 25. Alternatively, as shown in Figure 7, the sensor 60 includes a flow sensor located in the flexible tubing 24 to detect the flow rate of the fluid flowing through the flexible tubing 24. When the sensor 60 detects the rotation of the rollers 25 or the flow of the fluid, a sound is generated by the sound generating device 62. The frequency of the sound generated by the sound generating device 62 depends on the rotation speed of the rollers 25 or the flow rate of the fluid, which is determined by the rotation speed of the rollers 25. The sound includes a sequence of beeps, for example. Preferably, when the rotation speed or the flow rate increases, the frequency of the

beeps increases. In contrast, when the rotation speed or the flow rate decreases, the frequency of the beeps decreases.

[0032] This disclosure provides exemplary embodiments of a child safety blind. The scope of this disclosure is not limited by these exemplary embodiments. Numerous variations, whether explicitly provided for by the specification or implied by the specification, such as variations in shape, structure, dimension, type of material or manufacturing process may be implemented by one of skill in the art in view of this disclosure.